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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/568,108 | 02/13/2006 | Alexandre Avrameas | 62745.000020 | 5477 |
| 21967 | 7590 | 04/18/2007 | EXAMINER | |
| HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109 | | | HA, JULIE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 31 DAYS | 04/18/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/568,108 | AVRAMEAS, ALEXANDRE |
| | Examiner | Art Unit |
| | Julie Ha | 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. ____ .
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ . 5) Notice of Informal Patent Application
6) Other: ____ .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 3, 8 and 20, drawn to an amino acid sequence XBBXBXXBXBBXBXXB, SEQ ID NO:1, and the method of use of an amino acid sequence.

Group II, claim(s) 3 and 8, drawn to an amino acid sequence X_{(1)p}XBBBXBXBXBBXBXXB and SEQ ID NO:2.

Group III, claim(s) 21-26, drawn to a vector comprising at least one amino acid sequence.

Group IV, claim(s) 27, drawn to an eukaryotic cell containing an amino acid sequence.

Group V, claim(s) 27, drawn to an eukaryotic cell containing a vector.

Group VI, claim(s) 28, drawn to a biological, pharmaceutical, cosmetic, agro-food, diagnostic or tracking composition, comprising a vector as an active ingredient.

Group VII, claim(s) 28, drawn to a biological, pharmaceutical, cosmetic, agro-food, diagnostic or tracking composition, comprising an eukaryotic cell as an active ingredient.

Group VIII, claims 20 for the method of use of an amino acid sequence X_{(1)p}XBBBXBXBXBBXBXXB and SEQ ID NO:2.

It is noted that claim 20 recite the language "use of an amino acid sequence." "Use" claim language is improper under U.S. practice. Thus, for the purposes of this restriction, "use of an organic solvent" has been interpreted as a "method of use." Accordingly, claim 20 has been grouped as a method claim.

Linking Claims

2. Claims 1-2, 4-6, 9-19 and 28 link(s) inventions I, II and VIII. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1-2, 4-6, 9-19 and 28. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) a product and a process specially adapted for the manufacture of said product; or
- (2) a product and a process of use of said product; or

- (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) a process and a apparatus specifically designed for carrying out said process; or
- (5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process. 37 CFR 1.475.

Group I, having a first product and a first method for making said product fall within category (2). PCT Rule 13 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of making and the additional composition and method claims each constitute a separate group.

4. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The peptide sequences are different and therefore, each sequence is structurally distinct. There is no common structure present. For example, claim 2 recites the formula XBBXBXXBXBBXBXXB, and this peptide sequence according to claim 8 is LRRERQSRLRRERQSR (SEQ ID NO:1). Claim 3 recites formula (III) which can be XBBBXBXBXBBXBXXB, and this peptide sequence according to claim 8 is GAYDLRRRERQSRLRRERQSR. SEQ ID NOS: 1 and 2 are different and thus will give patentably independent and distinct structures. Further, there is no "core" sequence that belong to both SEQ ID NO: 1 and 2. SEQ ID NO: 2 comprises 2 more Arg and have Gly, Ala and Tyr residues. Further, search for one would not necessarily lead to the other.

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)
 - (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
 - (B)
 - (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Peptide of SEQ ID NO: 1 for Group I, or

Peptide of SEQ ID NO:1 and a second amino acid sequence for Group I
(corresponding to sequence deriving from an antibody fragment, deriving from
hypervariable region, deriving from the heavy chain of an antibody, an anti-DNA
antibody, CDR2, or CDR3 region of antibody),

Peptide of SEQ ID NO: 2 for Group II, or

Peptide of SEQ ID NO:2 and a second amino acid sequence For Group II
(corresponding to sequence deriving from an antibody fragment, deriving from
hypervariable region, deriving from the heavy chain of an antibody, an anti-DNA
antibody, CDR2, or CDR3 region of antibody),

Substance of interest chosen from: nucleic acid, protein, drug, antigen, antibody,
polymer, marker (fluorochrome);

Anchoring molecule: (the Examiner could not locate the species in the
specification nor the claims);

9. Applicant is required, in reply to this action, to elect a single species to which the
claims shall be restricted if no generic claim is finally held to be allowable. The reply
must also identify the claims readable on the elected species, including any claims
subsequently added. An argument that a claim is allowable or that all claims are
generic is considered non-responsive unless accompanied by an election.

10. For any Group elected that pertains to the amino acid sequence including vectors
and eukaryotic cells (i.e., Groups I-III and VIII), the Applicant is requested to elect a
single disclosed peptide species (e.g., SEQ ID NO) or SEQ ID NO and a second amino

acid sequence combination. For example, If Group I is elected, the Applicant is requested to elect for example, SEQ ID NO:1. If Group II is elected, the Applicant is requested to elect for example, SEQ ID NO:2 and sequence corresponding to hypervariable region. If Group III is elected, the Applicant is additionally requested to elect a single disclosed species from substance of interest chosen from, the anchoring molecule, and how a vector and substance of interest is coupled to each other. Again, by election of species, this means that Applicants should elect a single disclosed compound. Election of "formula II" or "formula III" is not species, but an election to a genus. An election of this nature will not be fully responsive to the election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. The claims are deemed to correspond to the species listed above in the following manner:

Claims 3-8, 10-16, 18, 24-26 and 28.

The following claim(s) are generic: Claim 1-2.

13. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The peptide compounds are different due to different amino acid compositions, and thus, having different structures. Further, search for one would not necessarily lead to the other. The location of where the second amino acid is derived from is patentably independent and distinct because the antibodies have different classes and different variable regions. Therefore, the sequence of the second amino acid sequence would be different, giving rise to different structures. Further, search for one would not necessarily lead to the

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other. Substance of interest is patentably independent and distinct because they all have very different structures. For example nucleic acid is made up of DNA or RNA, and protein is made up of amino acids and drug can be naturally extracted or organic compounds that can be synthesized. Further, search for one would not necessarily lead to the other. Anchoring molecule is patentably independent and distinct because this can be any protein, any part of the cell that act as an anchoring molecule, such as actin polymer. Further, search for one would not necessarily lead to the other.

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

15. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

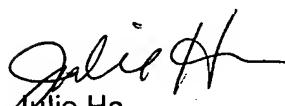
16. **Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.**

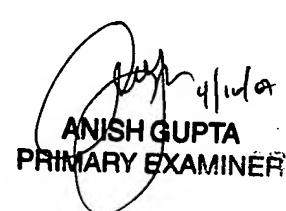
Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Julie Ha
Patent Examiner
AU 1654


ANISH GUPTA
PRIMARY EXAMINER